Healthpoint

Information from the Division of Health Care Finance and Policy

Argeo Paul Cellucci
Governor

William D. O'Leary
Secretary, Executive Office
of Health & Human Services

Division of Health Care
Finance and Policy

Two Boylston Street
Boston, MA 02116
(617) 988-3100

Barbara Erban Weinstein
Commissioner

Number 11 October 1998

HEALTH INSURANCE COVERAGE DECISIONS

The recent media spotlight on coverage of Viagra raises interesting questions regarding how and under what circumstances insurance companies cover new drugs and medical procedures. This issue of *Healthpoint* examines a number of factors affecting coverage decisions made by health insurance companies and self-insured employers in the Commonwealth of Massachusetts.

This analysis focuses on two case studies—human growth hormone (HGH) to treat short stature and autologous bone marrow transplant (ABMT) for breast cancer patients—to illustrate the complexity and competing pressures inherent in making coverage decisions. Specifically, these case studies suggest some of the difficulties in trying to uniformly apply clinical standards, as well as the role of non-clinical factors such as litigation, legislative mandates, cost, and public opinion in coverage decisions.

Making Coverage Decisions

The Division of Health Care Finance and Policy conducted an informal survey to examine the processes Massachusetts insurers and self-insured companies use to make coverage decisions. The National Committee for Quality Assurance (NCQA) requires that accredited managed care organizations (MCOs) adopt a formal process for evaluating when to cover a new health care service, procedure, or pharmacological treatment. However, NCQA does not detail how MCOs should structure this process, resulting in variation among insurers. In order to comply with the NCQA standard, many insurers have developed medical technology committees to analyze clinical, regulatory, legal, ethical, and actuarial issues related to coverage. While these committees draw on the expertise of a range of specialists, few appear to include direct member representation.

Within these formal structures, Massachusetts insurers use a range of analytic tools to make coverage decisions, including cost-benefit and cost-effectiveness analysis, polling, statistical studies, and competitor analysis. One insurer uses cost-effectiveness techniques to "evaluate the added value and cost of a newer therapy compared to a more conventional technology." Another medical director noted the importance of such techniques because "coverage decisions aren't black and white; the public doesn't realize how involved the process of making these decisions needs to be."

Usually, self-insured employers, whose plans cover nearly half of the 2.7 million Massachusetts HMO subscribers, rely on third party administrators (often MCOs) to

make coverage decisions for them. One employer stated, “the overriding principle is to listen to the expertise of our third party administrator, but not to follow it blindly.” A consultant suggested that when self-insured employers diverge from their administrators, it is often because a health issue has been brought to the attention of a company executive through personal experience or staff pressure.

Human Growth Hormone

All of the insurers and employers surveyed cover HGH and ABMT as part of their benefit packages. However, some require providers to obtain prior authorization for the patient before treatment is administered. While some survey respondents have estimated the incremental cost of covering both of these therapies, none quantified these costs for this publication.

Massachusetts insurers use medical necessity as the primary standard for assessing whether to cover a new therapy. Medical necessity implies that a treatment is essential for a patient’s physical or mental health, and that treatment complies with generally accepted medical practice. However, an analysis of HGH coverage illustrates the subjective nature of the term “medical necessity” and the limits inherent in applying it to determine coverage.

HGH is prescribed as a standard of care for children for three medical conditions that result in short stature: growth hormone deficiency, Turner syndrome, and chronic renal failure. Physicians also prescribe it for children with non-medical idiopathic (inherited) short stature. Generally, health insurers in Massachusetts cover HGH for the above mentioned medical conditions but not for idiopathic short stature. However, the primary goal of prescribing HGH for these conditions is to increase height, rather than to treat an underlying medical problem. Therefore, covering it even for the specific medical conditions may be difficult to justify on the grounds of medical necessity.

Furthermore, despite the high cost of HGH therapy and the relatively widespread coverage of it for medical conditions, the efficacy of this treatment remains in question. The drug must be injected every day for approximately ten years at a cost of $14,000-$30,000 per year. It remains difficult, however, to predict which children will respond to treatment. In fact, some studies show that HGH accelerates bone maturation in puberty which may impede future growth.

Finally, it appears that the medical necessity standard for covering HGH is frequently narrowed or broadened on an individual basis. On the one hand, insurers are under pressure not to cover expensive procedures that could be considered more cosmetic than medical. In contrast, the medical necessity definition is sometimes expanded to include idiopathic short stature, frequently on the basis of psychological health concerns. For example, parents of children with idiopathic short stature may view normal physical development as an important component of emotional well-being, and thus request that physicians prescribe HGH. In fact, one study found that 40 percent of HGH prescriptions were written for children with idiopathic short stature. However, insurers, one step removed from such influences, approve these claims only one percent of the time.

Autologous Bone Marrow Transplant

An analysis of ABMT with high dose chemotherapy for the treatment of breast cancer illustrates the unique nature of last chance therapy and the role of litigation, legislation, and public opinion in coverage decisions. This procedure involves extracting a patient’s bone marrow during high dose chemotherapy and re-infusing the marrow once the procedure is complete. The cost of this relatively risky procedure exceeds $100,000 as compared to conventional chemotherapy, which costs between $15,000 and $40,000.

The National Cancer Institute reports that ABMT may be superior to standard chemotherapy for advanced breast cancer, however, researchers currently lack definitive evidence to support this finding. Widespread availability of ABMT coverage preceded clinical evidence of efficacy in part as a result of a number of high visibility lawsuits. In 1992, for example, a California jury awarded $89 million to a man whose wife died of breast cancer after her insurer refused to pay for an ABMT. Such court rulings have encouraged insurers to prematurely include ABMT coverage in their benefit packages. In fact, ten states including Massachusetts currently mandate health insurers to provide ABMT coverage. Ironically, the availability of insurance coverage for ABMT has confounded efforts to complete large scale clinical trials to test its effectiveness because many women refuse to participate in trials for fear of being randomly assigned to a control group and thus barred from the treatment.

Without proven efficacy, a traditional cost-effectiveness analysis would likely preclude a decision to cover ABMT. One study calculated the cost-effectiveness ratio of the treatment at $97,000 per quality-adjusted life year saved (as opposed to the average charge of the treatment), a figure more than ten times that of routine chemotherapy. However, public outrage from high profile denials of care reflect the value Americans often place on a single human life, as well as the current negative HMO climate. This tension between cost-effectiveness and public sentiment highlights the difficulties inherent in reconciling cost-effectiveness with ethical considerations.

New Developments

With increasing frequency, an independent review process is used by insurers facing difficult individual coverage decisions. Most recently, California became the first state to require plans to establish a mandatory external review for individual appeals. The Friedman-Knowles Experimental Treatment Act, effective this July, mandated independent appeal for denials of experimental therapies for conditions likely to cause death within two years. Some insurers also are voluntarily adopting external review processes. For example, Empire Blue Cross Blue Shield of New York honors all requests by terminally ill patients for independent reviews on experimental treatment denials.

Independent appeals theoretically protect patients from decisions that prioritize cost control over care. Furthermore, some HMOs are beginning to view external reviews as protection against liability. From a policy perspective, external appeals laws provide an alternative to the piecemeal legislative health mandates that have proliferated over the last few years. In effect, these appeals aim at improving the decision-making process without mandating coverage of disease specific treatments.

According to a recent survey conducted by the Kaiser Family Foundation and Harvard University, 88 percent of the public favor the right to independent public review. Given its popularity, it is not surprising that an external appeal provision has appeared in Patient Bill of Rights legislation at both the federal level and within Massachusetts. In the Commonwealth, both the House and Senate approved external appeal provisions as part of pending HMO legislation. The House bill grants the reviewer narrow authority over whether care is required under the HMO contract's definition of medical necessity. In contrast, the Senate bill requires the independent reviewer to assess the medical necessity of the treatment, rather than solely evaluating whether it is required as part of the contract. The differences between these two bills have yet to be reconciled.

Federal legislative proposals also include external review provisions. As this publication goes to print, both Republican and Democratic versions of the HMO legislation include provisions for external appeal for denials of care. However, the Republican proposal limits external review to

disputes regarding medical necessity for treatments costing more than $1,000. If enacted, federal legislation would preempt state independent appeals provisions. This legislation could also potentially alter the ERISA law, and thereby apply to employees in self-insured plans.

Conclusion

Massachusetts insurers and employers have developed processes for evaluating whether to cover new therapies. Despite these processes, developing coverage policies remains as much an art as an exact science. These decisions impact the range of human experience from birth and child rearing to negotiating treatment for end-stage disease. In addition, human differences demand that coverage decisions be made on an individual as well as a categorical basis.

While medical necessity is the current guiding standard for defining coverage, the utility of this concept is limited by its vulnerability to interpretation. Non-clinical factors such as mandate legislation, litigation, and public opinion necessarily affect insurer decisions regarding coverage. The ultimate role these factors will play remains unclear.

By deferring to a financially disinterested party, independent reviews of appeals may be part of the answer. Over time, these reviews will likely become a more standard component of coverage decision-making. However, deciding coverage is inevitably an ethically challenging and politicized process often with significant financial repercussions. Furthermore, given the fast pace of technological innovation, these types of difficult coverage questions can only be expected to increase.

Did you know?

Foreign Patients Impact Massachusetts Hospital Revenue

Massachusetts hospitals are known and respected throughout the world for their high quality medical care. Many hospitals actively encourage foreign patients, who can be a significant source of revenue because they generally pay full charges for their medical care. In addition, average charges for foreign patients are substantially higher than for U.S. residents. While foreign patients visit Massachusetts hospitals for a wide variety of procedures, most come for the treatment of life-threatening conditions such as cancer and heart disease. The following tables highlight characteristics of foreign inpatients and the hospitals that care for them.

Characteristics of Foreign Inpatients, 1997	Foreign Patients	All Other Patients
Number of Discharges	654	769,954
Average Length of Stay	7.1 days	5.1 days
Average Charges	$22,688	$10,150
Average Age	48	49
Percent Male	57.6%	42.7%
Percent Female	42.4%	58.3%

Most Common Procedures for Foreign Inpatients, 1997	
Craniotomy (e.g., for malignant and benign brain tumors)	38
Coronary Bypass	19
Major Joint and Limb Reattachment	14
Major Chest Procedures (e.g., for throat and lung cancer)	14
Back and Neck Procedures (e.g., for intervertebral disc disorders)	12
Skin Graft	10

Hospitals with the Most Foreign Inpatients, 1997	
Massachusetts General Hospital	327
Brigham and Women's Hospital	128
Lahey Hitchcock Medical Center	68
All Others (26 hospitals)	131

Source: Massachusetts Division of Health Care Finance and Policy Fiscal Year 1997 Hospital Case Mix and Charge Database

Staff for this publication:

Colleen Barry
Laurie Felland
Didem Bernard
Cindy Richard
Maria Schiff
Heather Shannon